ABSTRACT. Objective. As part of a study of possible effects of early life otitis media on children’s development, we attempted to determine whether levels of language and communication skills at 1 and 2 years of age are associated with the cumulative duration of middle ear effusion (MEE) in the first 2 years of life.

Methods. Subjects (N = 2156) were followed at one of eight study sites in the Pittsburgh area. Middle ear status was monitored closely throughout the first 2 years of life. For each child, the cumulative percentage of days with MEE was estimated based on diagnoses at visits and interpolations for intervals between visits. For each child also, 1 or both parents completed the MacArthur Communicative Development Inventory–Words and Gestures (CDI–WG) when the child was 1 year of age and the MacArthur Communicative Development Inventory–Words and Sentences (CDI–WS) when the child was 2 years of age.

Results. Unadjusted correlations between scores on the CDI–WG and percentage of days with MEE in the first year of life were close to zero, and there were no statistically significant negative correlations. Unadjusted correlations between scores on the CDI–WS and the cumulative percentage of days with MEE in year 2 and in years 1 and 2 combined were generally negative and statistically significant, but the magnitudes of those correlations were no higher than 0.09. After adjustment for sociodemographic variables, only the Vocabulary Production Scale of the CDI–WS remained correlated significantly with the percentage of days with MEE, and the percentage of days with MEE accounted for only a negligible percentage of the variance in scores on this scale.

Conclusions. In this diverse sample of children, parent-reported levels of language skills at 1 and 2 years of age were correlated negligibly with the cumulative percentage of days with MEE in the children’s first and second years of life. Pediatrics 1999;104(4). URL: http://www.pediatrics.org/cgi/content/full/104/4/e52; otitis media, otitis media with effusion, language, communication.

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of time with elevated hearing thresholds, but these correlations were negligible or no longer significant when ratings of home and child care environments were considered in structural equation models.

Unfortunately, most of the studies of relationships between early development and otitis media have enrolled children at high risk for developmental impairments based on other risk factors, such as prematurity or low socioeconomic status. From such studies, it is difficult to determine the independent association of otitis media with speech, language, or communication because of the potential interactive or additive effects of multiple risk factors on developmental outcome. However, two prospective studies that evaluated healthy children from middle class families without apparent risk factors for delayed development also yielded conflicting results. Friel-Patti and Finizio found a number of statistically significant negative correlations between, on the one hand, scores on receptive and/or expressive language tests and, on the other hand, both the estimated number of days with OME and elevated hearing thresholds during antecedent periods at 12, 18, and 24 months of age. In contrast, Feagans and colleagues found no primary effects of the duration of otitis media on expressive or receptive language outcome.

As part of a prospective study of possible effects of early life otitis media on the development of children, the present study considered whether parent-reported levels of language and communication skills at 1 and 2 years of age were correlated negatively with the cumulative percentage of days with MEE during the antecedent periods. The study enrolled a large, healthy, and sociodemographically diverse sample of children. The choice of comprehensive parent report inventories allowed concurrent assessment of multiple aspects of nonverbal communication, receptive language, and expressive language with a single instrument.

METHODS

Participants

Subjects in this study were 2156 apparently healthy children who were enrolled in a large prospective study of possible relationships between early life otitis media and speech, language, cognitive, and psychosocial development. These children represent all those whose experience with MEE was reported previously by Paradise et al and whose parents, in addition, completed language inventories when the children reached 1 and 2 years of age. Table 1 describes selected sociodemographic characteristics of the sample.

All of the children presented for primary care at one of eight participating pediatric practice sites in the greater Pittsburgh area: two inner city hospital clinics, two small town or rural practices, and four suburban private practices. The children were enrolled in the parent study within the first 2 months of life. The institutional review boards of the Children’s Hospital of Pittsburgh and the Mercy Hospital of Pittsburgh approved the study. At the time of enrollment, a standardized medical and social history was obtained. Children were excluded from enrollment if they met any of the following criteria that could affect global or language developmental outcome adversely: birth weight <5 lbs (2268 g); small for gestational age; a history of neonatal asphyxia or other serious illness; a major congenital malformation or chronic illness; multiple birth; in foster care or adopted; mother dead, seriously ill, a known drug or alcohol abuser, or overwhelmingly limited socially or intellectually; mother <18 years of age; and English not the only language spoken at home. Thus, the sample at enrollment was limited to children with no recognized major biological or social risk factors for developmental delay other than low socioeconomic status. Children also were excluded if a sibling was participating in the study or if their parents planned to move away from the region within 5 years of enrollment.

At the time of enrollment, study personnel classified the infants’ ethnicity as either white, black, or other. Information about maternal education was obtained by asking the parent to indicate the mother’s highest level of academic achievement. Economic status was estimated broadly using health insurance status (Medicaid or private) as a proxy inasmuch as families of children enrolled in Medicaid must meet an income criterion and generally have lower family incomes than families of children enrolled in private health insurance. Table 1 shows that the sample was diverse in terms of maternal education, health insurance status, and race.

Procedures

Periodic Middle Ear Assessment and Treatment of Otitis Media

All subjects were scheduled for monthly observations at either well-child, illness, or follow-up physician visits, or visits made specifically for study purposes. At each visit, trained study personnel obtained a standardized interval history. Participating physicians or trained nurse practitioners performed a standardized ear examination using a pneumatic otoscope with airtight lens assembly (model 20200, Welch Allyn, Inc, Skaneateles Falls, NY). Until January 1995, tympanometry, using a GSI 33 Middle Ear Analyzer (Grason-Stadler, Inc, Milford, NH) was performed at

<table>
<thead>
<tr>
<th>TABLE 1. Distribution of Selected Sociodemographic Characteristics of Study Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristic</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Maternal education</td>
</tr>
<tr>
<td>&lt;High school graduate</td>
</tr>
<tr>
<td>High school graduate</td>
</tr>
<tr>
<td>High school graduate +</td>
</tr>
<tr>
<td>College graduate</td>
</tr>
<tr>
<td>College graduate +</td>
</tr>
<tr>
<td>Health insurance</td>
</tr>
<tr>
<td>Medicaid</td>
</tr>
<tr>
<td>Private</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Race</td>
</tr>
<tr>
<td>Black</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

High school graduate + indicates some college or technical school beyond high school or an associate degree. College graduate + indicates completion of postbaccalaureate study.

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each visit except when otorrhea was present. Thereafter, because of its limited positive predictive value, tympanometry was performed only when: 1) otitis media was diagnosed, suspected, or newly resolved; 2) the presence or absence of MEE was critical in a protocol-related decision; or 3) tympanometry was requested by a study team clinician. A forced choice decision was made and recorded for each ear concerning the presence or absence of acute (suppurative) otitis media, OME, or otorrhea through a tympanostomy tube. These three conditions were subsumed under the term MEE for purposes of analysis. In addition to ongoing interobserver comparisons at the Children’s Hospital of Pittsburgh, one of the authors possesses a protocol-related decision; or 3) tympanometry was requested by a study team clinician. A forced choice decision was made and recorded for each ear concerning the presence or absence of acute (suppurative) otitis media, OME, or otorrhea through a tympanostomy tube. These three conditions were subsumed under the term MEE for purposes of analysis. In addition to ongoing interobserver comparisons at the Children’s Hospital of Pittsburgh, one of the authors posses...

Cumulative Percentage of Days With MEE

For each child, we estimated the number of days on which unilateral and bilateral MEE, respectively, were present based on diagnoses at individual visits and interpolations for intervals between visits, provided that the intervals did not exceed 90 days. If the ear was effusion-free on two consecutive visits, we assumed that the ear contained no effusion during the period between visits. Similarly, if MEE was present on two consecutive visits, we assumed that MEE was present throughout the interval between visits. If the ear was effusion-free on one visit and contained effusion on the next visit, or vice versa, we assumed that effusion was present during one half of the interval between visits. We calculated the proportion of time with MEE for year 1 based on 365 days (from 2 months to 12 months of age) and for year 2 based on 365 days. Overall, the mean cumulative percentage of days with total MEE (bilateral plus unilateral) in the first year of life for this sample was 20.4% (standard deviation [SD]: 18.9%), and the median was 15.7%. The mean cumulative percentage of days with MEE in the second year of life was 16.5% (SD: 16.7%), and the median was 11.8%. Tympanostomy tube placement was performed on 1.7% and 4.3% of the children in the first and second years of life, respectively. The unadjusted mean cumulative percentage of days with MEE was higher among boys than among girls, higher among black children than among white children, and higher among Medicaid enrollees than among private insurance enrollees. The cumulative percentage of days with MEE varied directly with the number of smokers in the household, and the number of other children to whom the child was exposed either at home or in day care and varied inversely with maternal education, maternal age, birth weight, and duration of breastfeeding.18

Assessment of Hearing

Audiometric testing was scheduled in subjects after 8 continuous weeks of otitis media and at specified intervals thereafter in all randomized subjects at the time of randomization, in a sample of subjects free of otitis media, and in any subject in whom a parent or clinician suspected hearing loss. Audiometric findings will be reported separately.

Assessment of Language and Communication

We assessed language and communication skills using two comprehensive parent report measures that were termed collectively the MacArthur Communicative Development Inventories (CDIs).22 We used parent report measures because of the large sample size and the difficulties entailed in testing infants and toddlers directly in the clinic or laboratory.

Assessment at 1 Year of Age

Parents completed the MacArthur Communicative Development Inventory—Words and Gestures (CDI-WG) at or near their children’s first birthday at an average age of 12.04 months. The CDI-WG, a measure appropriate for children 8 to 16 months of age, assesses receptive verbal language, expressive vocabulary, and nonverbal communicative and symbolic actions. The CDI-WG contains two types of scales: one type elicits categorical responses, of either the yes/no or often/sometimes/never variety and the other type elicits continuous interval scores based on a checklist format. The categorical scales are based on relatively few items, whereas the continuous scales are based on a list of 28 pairs of words such as “wave/eye,” “wicky/sleepy.” 1 Vocabulary Comprehension counts the number of words that the child understands from a list of 396 words commonly found in the receptive vocabularies of young children, including animal names, animal noises, and foods; 3 Vocabulary Production counts the number of words that the child actually says, whether pronounced accurately or inaccurately, from the same vocabulary list; and 4 Total Scores generates the number of nonverbal communicative acts and symbolic or imitative actions from a list of 63. Assessment at 2 Years of Age

Parents administered the MacArthur Communicative Development Inventory—Words and Sentences (CDI–WS) at or near their children’s second birthday at an average age of 24.06 months. The CDI–WS, appropriate for children 16 to 30 months of age, evaluates expressive vocabulary, early grammatical skills, and sentence length. Like the CDI–WG, the CDI–WS contains both categorical and continuous interval scales. For the same reasons as with the CDI–WG, we excluded the categorical scales of the CDI–WS from the present analysis. The five continuous interval scales of the CDI–WS are scored independently: 1 Vocabulary Production counts the number of vocabulary items that the child says from a list of 25 words found commonly in the expressive vocabularies of young children; 2 Word Forms–Irregular scores the number of selected irregular plural forms such as mice or houses and past tense forms such as ate from a list of 25 words; 3 Word Forms–Overregularized scores the number of mistakes that the child makes by applying an ending incorrectly such as children and aed; 4 Three Longest Sentences asks parents to generate the three longest sentences they heard their child produce and scores the average number of words and morphemes (meaningful parts of words, such as “s” or “ed” at the end of words) in these sentences; and 5 Sentence Complexity counts the number of mature forms typical of the child’s sentences from a list of 37 sentence pairs that hold meaning constant and vary in grammatical complexity (such as “kitty sleeps” vs “kitty sleep”).

Measurement Properties of the CDIs

We previously found significant linear trends with increasing monthly age in scores on the continuous interval scales of both the CDI–WG and the CDI–WS confirming that the inventories were able to detect developmental trends in the age ranges we studied.23 Nonetheless, on several scales of both the CDI–WG and the CDI–WS, SDs approximated or exceeded mean values, reflecting wide variability in results at these ages. On both the CDI–WG and the CDI–WS, statistically significant differences in mean scores were found according to race, maternal education, and health insurance status, but the directionality of differences was not consistent. Paradoxically, on the CDI–WG, scores on all three verbal language sections were higher for children whose mothers had lower educational status than for those whose mothers had higher educational status, and higher for those with Medicaid insurance than for those with private insurance. By contrast, on the CDI–WS, scores on some scales (Vocabulary Production, Three Longest Sentences, and Sentence Complexity) were higher for children whose mothers had higher educational and income levels than for children whose mothers had lower educational and income levels, whereas on other scales (Word Forms–Irregular and Word Forms–Overregularized), the scores were higher for children whose mothers had lower educational and income levels. Nonetheless, these sociodemographic variables, generally thought to be associated highly with language outcome,24 accounted for a negligible amount of the variance in scores.
Correlations between scores on the CDI and cumulative percentage of days with total MEE and with bilateral MEE were calculated separately for year 1, year 2, and years 1 and 2 combined, using Pearson product moment correlations because the assumptions of normality were met. Because we previously had found significant linear trends in scores with increasing monthly age, and also significant differences in mean scores according to race, maternal education, and health insurance status,2 we also used multivariate regression to examine whether scale scores remained significantly correlated with percentage of time with MEE after adjusting for all these variables.

RESULTS

Correlations Between Scores on the CDI–WG and Cumulative Percentage of Days with MEE

Mean scores (and SDs) on the four continuous scales of the CDI–WG for the sample as a whole were as follows: Phrases Understood, 15.6 (SD: 6.4); Vocabulary Comprehension, 100.3 (SD: 76.6); Vocabulary Production, 9.9 (SD: 15.2); and Total Gestures, 25.3 (SD: 9.4). Table 2 shows unadjusted correlations between scores on the CDI–WG and the cumulative percentage of days with total MEE and bilateral MEE in the first year of life. Correlations ranged from −0.006 to 0.052; only a single correlation achieved statistical significance, and it was positive rather than negative. After adjusting for age in months, sex, race, maternal education, and health insurance status, percentage of time with total MEE was significantly correlated negatively only with Phrases Understood \( (P = .01) \) and with Vocabulary Comprehension \( (P = .04) \). However, in the regression models, all six variables together accounted for only 3.7% of the variance in Phrases Understood and 4.0% of the variance in Vocabulary Comprehension. Findings regarding percentage of days with bilateral MEE were closely similar.

Correlations Between Scores on the CDI–WS and Cumulative Percentage of Days With MEE

Mean scores (and SDs) on the five continuous scales of the CDI–WS for the sample as a whole were as follows: Vocabulary Production, 293 (SD: 175.2); Word Forms–Irregular, 5.4 (SD: 5.3); Word Forms–Overregularized, 3.0 (SD: 5.1); Three Longest Sentences, 3.7 (SD: 1.9); and Sentence Complexity, 9.7 (SD: 8.5). Table 3 shows unadjusted correlations between scores on the CDI–WS and cumulative percentage of days with total MEE and with bilateral MEE during both the second year of life and the first and second years of life combined. Correlations were low ranging from −0.086 to 0.010. After adjusting for monthly age, sex, race, maternal education, and health insurance status, percentage time with total MEE in year 2 was significantly correlated negatively only with Vocabulary Production \( (P = .03) \) with all variables together accounting for only 3.8% of the variance in the scores on this scale. Findings regarding percentage time with bilateral MEE in year 2 were closely similar, as were findings regarding percentage of time with total MEE and with bilateral MEE in years 1 and 2 combined.

DISCUSSION

In summary, we found no statistically significant negative correlations between parent reports of the level of language and communication skills at 1 year of age and the cumulative percentage of days with MEE in the first year of life. We did find statistically significant negative correlations between parent reports of language skills at 2 years of age and the percentage of days with total or bilateral MEE in the second year of life and in the first two years of life combined. However, these correlations were weak and the only correlation that remained significant after adjusting for age and other pertinent variables was with vocabulary production. In all cases, the amount of variance in parent-reported levels of language and communication skills accounted for by all variables, including percentage of time with MEE, was negligible.

This study had a number of strengths. We enrolled a much larger and more sociodemographically diverse sample of children than were enrolled in previous studies of relationships between otitis media and language development in this age range. Children with known risk factors for adverse developmental outcomes such as prematurity or low birth weight were excluded systematically from the sample. Finally, otoscopy, supplemented by tympanometry, was used to diagnose MEE, and the accuracy of otoscopic diagnoses was subjected to systematic interobserver appraisal.

Our results were consistent with those of Feagans and colleagues12–14 and Wright and colleagues,14 who found that the frequency of otitis media was not associated with scores on language measures. Our findings are also similar to those of Roberts and colleagues,15,16 who found that apparent associations between otitis media and language scores could be attributed to the quality of the caregiving environment rather than to the duration of otitis media per se. By contrast, Friel-Patti and Finitzo6 reported statistically significant associations between both receptive and expressive language and the duration of

### TABLE 2. Unadjusted Correlations Between Scores on the CDI-WG and Cumulative Percentage of Days With Total and With Bilateral MEE in Year 1

<table>
<thead>
<tr>
<th>CDI–WG Scales</th>
<th>Percentage of Days Total MEE Year 1</th>
<th>Percentage of Days Bilateral MEE Year 1</th>
<th>( r ) values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phrases Understood</td>
<td>−.033</td>
<td>−.016</td>
<td></td>
</tr>
<tr>
<td>Vocabulary Comprehension</td>
<td>−.006</td>
<td>−.005</td>
<td></td>
</tr>
<tr>
<td>Vocabulary Production</td>
<td>.052*</td>
<td>.028</td>
<td></td>
</tr>
<tr>
<td>Total Gestures</td>
<td>−.018</td>
<td>−.018</td>
<td></td>
</tr>
</tbody>
</table>

* \( P < .02 \)
antecedent otitis media accounting for ≤4% of the variance in scores. However, that study was limited by the following facts: 1) enrollment at 6 months of age could have missed information about earlier experience with OME; 2) tympanometry, the primary method used to detect OME, has limited specificity; and 3) correlational analyses excluded the 26.5% of the study population who experienced no OME between 6 and 18 months of age.

A limitation of our study was our use of parent report inventories, namely the CDI–WG and CDI–WS, as the exclusive measure of language and communication development. Parent reports are avoided frequently in research because of the following reasons: 1) parents lack formal training in the domain of interest, in this case language development, and therefore may be insensitive to subtle features of their children’s language use and 2) because parents’ attitudes, beliefs, or pride may lead them to overestimate their children’s abilities. Certain limitations of the CDI–WG and the CDI–WS specifically are summarized above. Accordingly, these measures may not be sufficiently sensitive for detecting differences in outcomes in relation to percentage of days with MEE. In contrast, parent reports are integral components of other assessment measures of young children including the Sequenced Inventory of Communicative Development that has been used in a number of other studies of possible relationships between language development and antecedent otitis media. Finally, any method of language and communication assessment for infants and toddlers is likely to have important limitations because the evaluation of young children is inherently difficult. Although we did not assess the validity of the measures that we used by concurrently testing a subset of the study sample directly, we may be able to assess the predictive validity of our findings by measuring the degree of association between the parent reports at 1 and 2 years of age and direct assessment of the children at older ages.

Before embarking on the present analyses, we had speculated that if early life otitis media indeed disrupts language development in later childhood, the effects might be most apparent early in the development of communication and language skills, when children are just beginning to learn these skills. However, based on our findings in this large and diverse population, we wonder whether these very early stages of language and communication development may be inherently so variable as to render it virtually impossible to detect the influence of any potentially influential factors. Currently, we are testing selected subgroups of our study population directly at 3, 4, and 6 years of age in an effort to determine whether possible developmental effects of early life otitis media emerge at these later ages.

ACKNOWLEDGMENTS

This work was supported by Grant HD26026 from the National Institute for Child Health and Human Development and the Agency for Health Care Policy and Research; by Grant MCJ 429414 from the Maternal and Child Health Bureau; and by gifts from SmithKline Beecham Laboratories, Pfizer Inc, and the Mattel Foundation.

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In addition to those above, the following persons served as study-team clinicians: at Children’s Hospital of Pittsburgh, Irene Fabian, CRNP; Nancy J. Guerra, CRNP; Beverly S. Bernard CRNP; and Alejandro Hoberman, MD; at Beaver, Allen H. Chamovitz, MD; Sharon N. Cowden, MD; Valentina E. DiCenzo, MD; Verda S. Graf, BS, PA; S. Nasrin Ghorbanian, MD; George R. Haddad, MD; Janet D. Lijestrand, MD; and Jennifer J. Momen, MD; at Brentwood, Norman L. Cohen, MD; Kristin L. Frederick, MD; Joan Schiebel, RN; and Brenda E. Watkins, MD; at Kittanning, Tracy Balentine, RN; Shirley Baum, CRNP; Lawrence J. Butler, MD; Thomas G. Lynch, MD; and JoAnn Nickleach, MD; at Mount Lebanon, Barbara J. Bahl, CRNP; Barbara Braman, CRNP; and Maria Bridgetta Devlin, CRNP; Holly A. Frost, MD; Lisa M. Hako- Zoffel, CRNP; Thelma L. Herlich, MD; and Elizabeth H. Michael, CRNP; at Pleasant Hills, Todd H. Wolynn, MD; and at Mercy Hospital of Pittsburgh, Barbara L. Ayars, MD; Kimberly Brown, MD; Michael J. Daly, MD; Karla Falcon, MD; Pamela Heald, CRNP; Cynthia M. Hoess, MD; Barbara L. McNulty, CRNP; Yolanda Moore-Forbes, MD; Charles A. Pohl, MD; Sharon M. Roncevich, MD; Sherrill J. Rudy, CRNP; Evelyn S. Palochak, RN; Sarah H. Springer, MD; and Karen S. Vargo, MD. We also thank the many pediatric house officers of the Children’s Hospital of Pittsburgh and Mercy Hospital of Pittsburgh who served as primary care clinicians for study subjects and whose collaboration was essential for the successful conduct of the study.

In addition to the authors, the following persons participated integrally in the planning and assisted in the implementation of this study: Charles D. Bluestone, MD; Robert J. Nozza, PhD; Howard E. Rockette, PhD; Diane L. Sabo, PhD; and Clyde G. Smith, MS.

The following people also assisted in the study: Ida Smith

TABLE 3. Unadjusted Correlations Between Scores on the CDI–WS and Cumulative Percent of Days With Total and With Bilateral MEE in Year 2 and in Years 1 and 2 Combined

<table>
<thead>
<tr>
<th>CDI-WS Scales</th>
<th>Percentage of Days With Total MEE (Year 2)</th>
<th>Percentage of Days With Bilateral MEE (Year 2)</th>
<th>Percentage of Days With Total MEE (Years 1 and 2)</th>
<th>Percentage of Days With Bilateral MEE (Years 1 and 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vocabulary Production</td>
<td>−0.68**</td>
<td>−0.72***</td>
<td>−0.69**</td>
<td>−0.78***</td>
</tr>
<tr>
<td>Word Forms–Irregular</td>
<td>−0.33</td>
<td>−0.043*</td>
<td>0.046</td>
<td>−0.047*</td>
</tr>
<tr>
<td>Word Forms–Overgeneralization</td>
<td>0.001</td>
<td>0.024</td>
<td>0.010</td>
<td>0.007</td>
</tr>
<tr>
<td>Three Longest Sentences</td>
<td>−0.050*</td>
<td>−0.037</td>
<td>−0.066*</td>
<td>−0.062*</td>
</tr>
<tr>
<td>Sentence Complexity</td>
<td>−0.070**</td>
<td>−0.085*</td>
<td>−0.086***</td>
<td>−0.076*</td>
</tr>
</tbody>
</table>

* P < .05; ** P < .01; and *** P < .001.
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Parent-reported Language and Communication Skills at One and Two Years of Age in Relation to Otitis Media in the First Two Years of Life
Heidi M. Feldman, Christine A. Dollaghan, Thomas F. Campbell, D. Kathleen Colborn, Marcia Kurs-Lasky, Janine E. Janosky and Jack L. Paradise

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